

## **REMARKS**

In the 24 February 2010 Office Action, the Examiner rejects all pending claims. Applicants thank the Examiner for the careful consideration and examination of the claims. No new matter is believed introduced as all modifications are supported by the Specification.

Applicants file this response solely to facilitate prosecution. Applicants reserve the right to pursue claims of broader or similar scope as originally filed in this application, a continuation application, or other application in the future. Applicants do not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter.

After entry of this Response, Claims 39-50 remain pending. Applicants respectfully assert that all pending claims are in condition for allowance, and respectfully request reconsideration of the claims in light of the following remarks.

### **I. Claims 39-45 & 49-50 Are Patentable Under § 112**

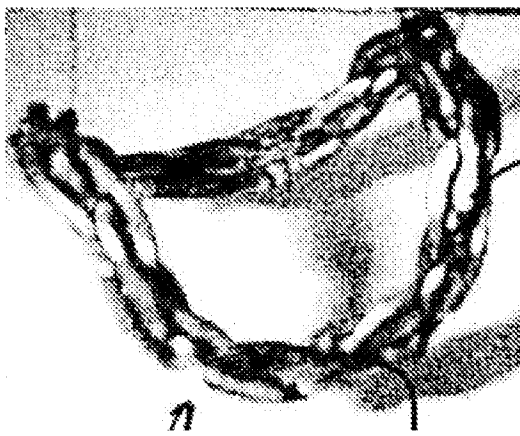
The Examiner rejects Claims 39-45 and 49-50 under § 112, ¶ 2 as allegedly being indefinite. Applicant follows the Examiner's suggestions regarding modifying certain claims. As to the Examiner's concerns about the use of "normal chordal force distribution" in certain claims, Applicant revises these claims to recite other inventive features. Disclosure supporting these changes may be found in Paragraphs 113-119 and Table I. As discussed therein, testing of prototype embodiments enables the claimed reduction of forces.

As a result, Applicants believe that the claim modifications address the Examiner's concerns. Withdrawal of the § 112 rejections is therefore respectfully requested.

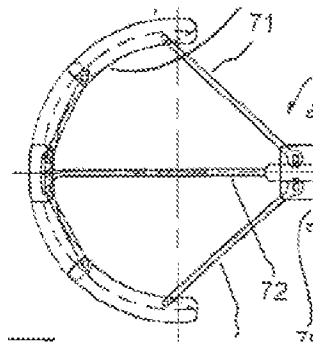
### **II. Claims 39-50 Are Patentable Over Quijano**

The Examiner rejects the pending claims under §§ 102-103 as allegedly unpatentable over Quijano (USPUB 2003/0050693). While Applicants believe their invention is more general, for the purposes of the present Application, Applicants clarify certain claims. Based on the claim modifications and the below remarks, Applicants respectfully traverse the rejection.

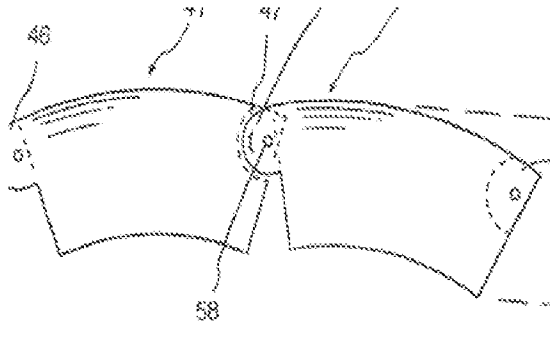
As currently claimed, Applicants' invention claims numerous features not taught, fairly suggested, or achievable by Quijano. While Quijano discusses his version of an annuloplasty ring, his ring is different from Applicants' claimed rings for a number of reasons. As shown below and as claimed, Applicants' rings are continuous, full rings capable of being deformed three dimensionally. Quijano's ring lacks these claimed features. Quijano merely describes a partial ring that can only deform in two dimensions. (Quijano, ¶¶ 10, 30, 35-39). Because Quijano's described ring is not a complete ring but only a partial ring, it can only create a shape on a posterior section of the annulus. As a result, it can not mold to a complete annulus perimeter like Applicants' claimed rings. Given these deficiencies, Applicants' pending claims are patentably distinct over Quijano.



*Sample of Applicants' 3D Ring*



*Quijano Partial Ring*



*Quijano's Coupling Prevents 3D Action*

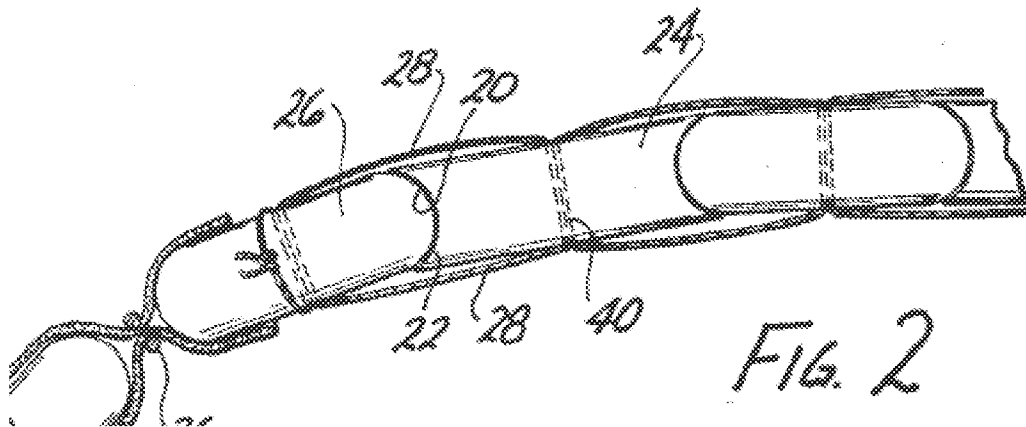
Regarding the Examiner's comment about Quijano teaching multiple shapes (in ¶ 42), Applicants believe this scant description does not enable someone to produce Applicants' claimed rings and overstates Quijano. This is especially true when considering Quijano's specific coupling arrangement (as shown above) that prevents 3-D movement and only allows 2-D movement. Quijano describes this restricted movement as follows: "When two segments are at their secured state, the segments are restricted to flex inwardly along the circumferential plane." (Quijano, ¶¶ 35-36). Clearly restriction of movement along a plane is not 3-D movement. Even if Quijano's ring were extended to a "circular shape," its specific coupling arrangement only allows such a ring to flex 2-D – not 3-D. If one were to force 3-D operation on such a ring, Applicants respectfully assert that doing so would cause such a ring to mechanically fail and function improperly. Forcing a reference to operate in an inoperable condition weighs against obviousness. See MPEP § 2143.01 (V)-(VI).

Thus, it is believed that Quijano fails to teach or fairly suggest a ring having 3-D flexibility characteristics. For at least these reasons, Applicants believe the pending claims are allowable. Withdrawal of the rejections based on this reference is respectfully requested.

### **III. Claims 39-50 Are Patentable Over Carpentier & Wright**

The Examiner rejects the pending claims under §§ 102-103 as allegedly unpatentable over Carpentier (USPN 4,917,698) individually and in combination with Wright (USPN 5,201,880). While Applicants believe their invention is more general, for the purposes of the present Application, Applicants clarify certain claims. Based on the claim modifications and the below remarks, Applicants respectfully traverse the rejection.

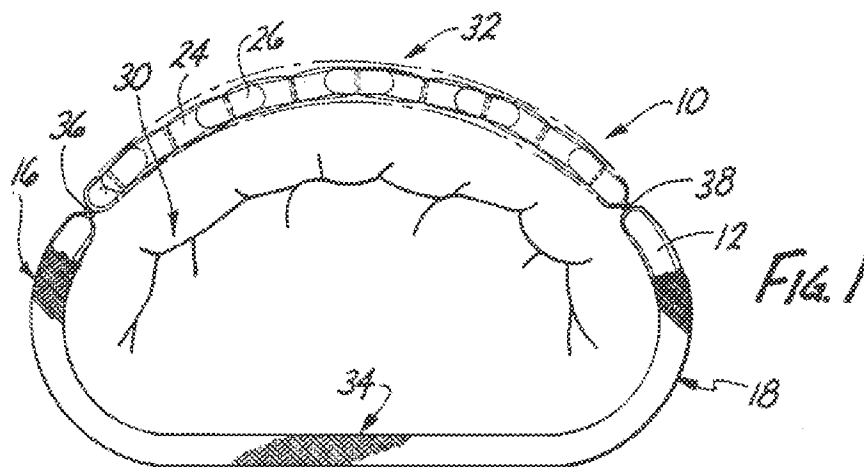
Carpentier describes a multi-segmented annuloplasty ring prosthesis. As shown below, Carpentier's ring includes segments 26, 24 placed and held in close proximity to each other. The segments do not have ends that are directly physically attached to each other. Rather, "the ends of adjacently positioned segments 24 and 26 [have] complementary shaped ends" that allows the segments to flex relative to each other. (Carpentier, c. 6, ll. 1-25).



Carpentier also lacks other claimed features. For example, Carpentier's ring is not comprised of a plurality chain links that form a full, continuous chain ring. Instead, Carpentier's ring has two segments, only one of which has the above-illustrated end-to-end segments 24, 26. Also, Carpentier's device utilizes a flexible, covering material to hold to fit snugly around Carpentier two segments. (Carpentier, Abstract). By doing this, Applicant believes that Carpentier's device can not three-dimensionally deform as claimed because Carpentier's device

can not achieve a constant perimeter. As a result, the pending claims are believed to be patentably distinct over Carpentier.

As for the Examiner's assertion that connections 36, 38 appear to inherently allow the device to assume a saddle shape capable of 3-D deformation with a constant perimeter, Applicant respectfully disagrees. Carpentier states that the ring prosthesis shown below includes a major portion of the ring formed of a substantially "rigid" segment and a number of smaller segments. (Carpentier, c. 5, ll. 14-16). "In particular, ring prosthesis 10 includes a first substantially rigid segment 12." (Carpentier, c. 5, ll. 17-18). Because segment 12 is substantially rigid, ends (16, 18) of the segment "may be deflected towards each other by the application of force." (Carpentier, c. 5, ll. 26-29). Applicant respectfully submits that because segment 12 is formed of a rigid element, that Carpentier's ring can not deform three-dimensionally and also can not form a saddle shape, as claimed. Also, applicant submits that such an arrangement teaches away from the claimed 3-D features because rigidity prevents 3-D movement as claimed.



Now turning to Wright, Applicant respectfully asserts that Wright fails to cure Carpentier's deficiencies. The portion of Wright cited by the Examiner states that someone's previous work "show[ed] that the mitral valve annulus is a complex and mobile structure and demonstrated that the mitral valve takes the form of a central, elliptical portion of a hyperbolic paraboloid or saddle shaped surface." (Wright, c. 3, ll. 42-46). While this statement makes clear that someone determined that the mitral valve can take on an annulus shape, it does not teach or fairly suggest to someone how to make an annuloplasty ring capable of forming a saddle shape. Wright offers no guidance on how to modify Carpentier's device to form a saddle shape. Merely observing that a valve can take on a certain shape without any additional details would not enable

one of skill in the art to modify Carpentier's device to yield a saddle shape. This is because Wright provides no details on how to provide the claimed rings and teaches away from such features due to its "rigid" construction.

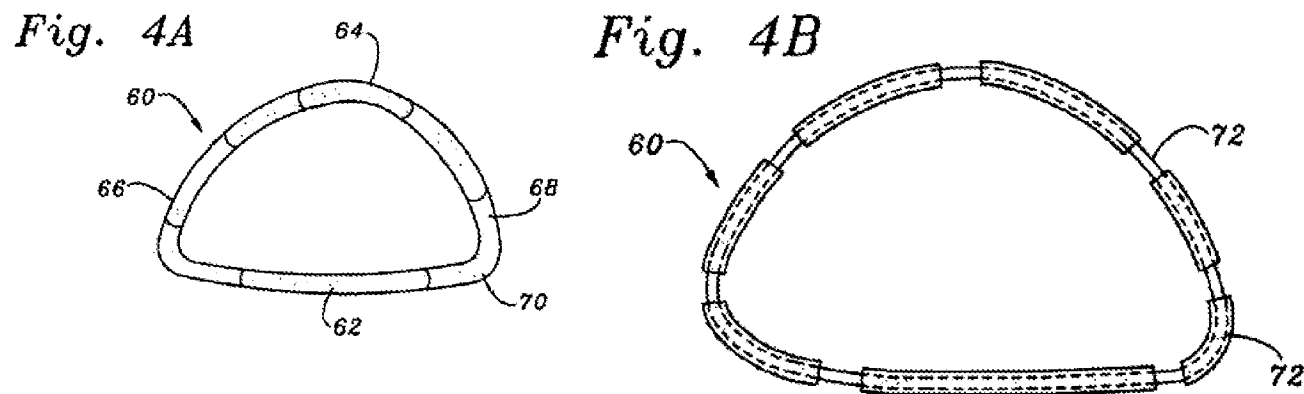
For at least these reasons, the pending claims are allowable over Carpentier and Wright. Withdrawal of the rejections based on these references is respectfully requested.

#### **IV. Claims 39-50 Are Patentable Over Marquez & Wright**

The Examiner rejects the pending claims under §§ 102-103 as allegedly unpatentable over Marquez (USPUB 2003/0040793) individually and in combination with Wright (USPN 5,201,880). Based on the pending claims, Applicants respectfully traverse the rejection.

Marquez describes a self-molding annuloplasty ring. As shown below, Marquez's ring in Figures 4A-4B show a ring 60 in concert with a several support members 70. Figure 4A shows the ring 60 in a contracted state and Figure 4B shows the same ring 60 in a stretched state. Each of these figures confirm that Marquez's ring is not comprised of a chain having a plurality of links with ends directly coupled to each other as claimed. Rather, these figures and associated text make clear that Marquez's ring is formed a single-looped material.

As to the support members 70, these items are not chain links either. Support members 70 are used for contraction control. But these items are not chain links as claimed since they lack ends directly coupled to each other. If they possessed such a feature, then the support members 70 would not allow Marquez's ring to move between a stretched state and a contracted state.



The Examiner's dependence on Wright for a Marquez/Wright combination also fails to render the pending claims unpatentable for other reasons. Wright does not teach or fairly suggest how one can make a ring have a saddle shape. All Wright states is that someone observed that an

annulus can form a saddle shaped surface. Further, Marquez's support members 70 prevent Marquez device from being three dimensionally deformed and from forming a saddle shape. Indeed, because the "support members 70 constrain contraction [of the ring] to a contracted diameter that is larger than the fully relaxed diameter," Marquez can not deform three dimensionally.

For at least these reasons, the pending claims are allowable over Marquez and Wright. Withdrawal of the rejections based on these references is respectfully requested.

#### **V. Fees & Express 3-Month Extension Request**

Applicant files this Response within six months of the 24 February 2010 Office Action with no additional claims. Applicant respectfully petitions for a 3-month time extension pursuant to 37 C.F.R. § 1.136 and submits the extension fee via EFS-Web. If any additional fees are deemed due for full acceptance of this submission and to keep this Application pending, the Commissioner is authorized to charge any fees to Deposit Account No. 20-1507.

#### **VI. Conclusion**

This Response is believed to be a complete response. Applicant respectfully submits that after entry of this Response the Application is allowable. The Examiner is invited to contact Hunter Yancey at 404-885-3696 if any other issues remain prior to the allowance of this Application. Early and favorable action is respectfully requested.

Respectfully submitted,

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